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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,384	11/03/2005	Paul Leonard Greenhaff	27053-17244	5375

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EXAMINER	
KRISHNAN, GANAPATHY	
ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
01/21/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTOC@Fenwick.com

Office Action Summary	Application No.	Applicant(s)	
	10/549,384	GREENHAFF ET AL.	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *112-162* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *112-162* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/10 and 9/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 10/15/2010 has been received, entered and carefully considered. The following information has been made of record in the instant amendment:

1. Claims 1-111 have been canceled.

2. Claims 112, 128 and 144 have been amended to recite the terms "or an analogue thereof".

3. Remarks drawn to support for the claim amendments.

Claims 112-162 are pending in the case.

The following have been overcome:

4. The rejection of Claims 112-118, 120-134, 136-150 and 152-162 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising L-carnitine and glucose, sucrose or fructose, and amino acids and the method of increasing carnitine retention using the said composition, does not reasonably provide enablement for a composition comprising any other agent and its use in the method as instantly claimed has been overcome in view of applicants' arguments filed 9/17/2010 and Interview on Oct. 07, 2010.

5. The rejection of Claims 112-162 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been overcome in view of applicants arguments and Exhibit A. Applicants arguments and Exhibit A are persuasive regarding the agents well known in the art for increasing insulin concentration as recited in claims 112, 128 and 144. The term "simple' recited previously in claim 117 and other claims has been deleted. Claim 160 has been amended to recite administration to a human and/or animal in need thereof.

6. The rejection of Claims 112-162 under 35 U.S.C. 102 as being anticipated by Pola (WO 01/95915, of record) has been withdrawn. The ratio of carbohydrates (ribose, dextrose and fructose-the agents) to L-carnitine in the compositions taught by Pola is not 10:1 as recited in claim 112. Thus Pola is not seen to anticipate each and every limitation of instant claims 112-116.

The following new art rejections are made of record.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 112-162 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 112 recites the term analogue thereof. In the absence of the specific analogues recited via chemical structures or the chemical names, the identity of said analogs would be difficult to define and the metes and bounds of the said analogs applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in this and all other claims in which the said terms are recited. In the absence of a definition for the analogs in the claims or in the specification the said term is examined as drawn to any substance that has a L-carnitine moiety attached to it. The said terms are recited in claims 112, 128 and 144.

Claims 113-127, 129-143 and 145-162 which depend from base claims that are unclear/indefinite are also rendered unclear/indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 112-116, 118-122 and 161 are rejected under 35 U.S.C. 102(b) as being anticipated by Iaccheri et al (US 4,753,804; newly cited).

Iaccheri et al teaches a composition comprising L-carnitine (500 parts by weight), glucose and fructose (both 5000 parts by weight; both are agents that increase insulin concentration; col. 10, Example 6). The ratio of L-carnitine to glucose or fructose is 10:1 (limitations of claims 112, 120-122). The glucose and fructose (both are carbohydrates: agents as instantly recited) present in the composition read on the limitations of claims 113-116, 118-119. The composition of Iaccheri is prepared in the form of a pellet. This reads on the limitation of claim 161.

Claims 112, 115, 117, 126-127, 144-154 and 158-160 and 162 are rejected under 35 U.S.C. 102(b) as being anticipated by Brantman (US 4,687,782; newly cited).

Brantman teaches a composition (Example 1, cols 5-6) in which L-carnitine is 0.025g, soy protein is 2.5g (the agent). The ratio of agent to L-carnitine is at least ten to one. This reads

on part of the limitation of claim 115). The same composition also has the amino acids isoleucine, leucine and valine. The amount of these amino acids is at least ten times that of L-carnitine (part of the limitations of claim 115 and limitation of claim 117).

The above composition of Brantman has sucrose as one of the ingredients (25g). This is the agent to increase insulin concentration. The composition is made up as a unit in 400 ml of water (col. 5, lines 55-57). Sucrose is present at a concentration of 25g/400ml water, which is 60mg/ml. These teachings read on the limitations of claims 126-127, 144-151 and 158-159. The amount of sucrose is at least ten times that of L-carnitine (limitations of claims 152-154). The amounts of amino acids (which are also agents that increase insulin concentration) are 34 times that of L-carnitine (reads on limitations of claims 152-154).

Brantman's composition is for facilitating the adaptation of skeletal muscles in humans. Muscles require carnitine (abstract; col. 1, lines 33-38; col. 1, lines 54-60; col. 2, lines 61-63; Example 1 at cols. 5-6). The composition is for oral administration (col. 4, lines 62). This teaching is seen to read on claims 160 and 162.

Claims 112-116, 118, 120-126, 128-132, 134, 136-142 and 155-157 are rejected under 35 U.S.C. 102(b) as being anticipated by Pola (WO 01/95915).

Pola teaches a composition comprising L-carnitine, propionyl carnitine, acetyl carnitine, and isovaleryl carnitine (analogs of carnitine), each 250mg and ribose 2.5g (the agent to increase insulin concentration). It can be seen that the ratio of ribose to each of L-carnitine and the analogs is 10:1 (page 7, composition # 7).The compositions can be made as a syrup (page 10, line 2; same as solution). This teaching of Pola is seen to read on the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims123-125, 128-143 and 155-157 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pola (WO 01/95915; of record) in view of Brantman (US 4,687,782; newly cited) and Iaccheri et al (US 4,753,804; newly cited).

Pola's and Brantman et al 's teaching are as above. Pola teaches the use of 0.25g of L-carnitine which is the lower end of the range recited for L-carnitine in the instant claims. Brantman teaches that in the composition of his invention L-carnitine can be used in the range of 0.3 to 2.0g (col. 4, lines 45-47). The ranges of amino acid proportions may be varied to refine to adaptive responsiveness (col. 5, lines 3-9). One of ordinary skill in the art will recognize from this teaching that the composition can be made with different amounts of L-carnitine as needed including the amounts instantly claimed and the amount of the agent can be adjusted to be at least ten times or more compared to that of carnitine, since a composition comprising such a ratio is taught.

Iaccheri's teaching is as above. Specifically he teaches the use of glucose and fructose (agents recited in instant claim 135) in his composition which is similar to the composition of Brantman.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition as instantly claimed since analogous compositions comprising the components of the instant composition in the proportions claimed are taught in the prior art. The proportions can also be varied according to individual needs according to the prior art.

One of ordinary skill in the art would be motivated to make the claimed compositions containing the claimed proportions since the components including L-carnitine and the other amino acids maximize protein synthesis in skeletal muscles (Brantman, col. 4, lines 22-30).

MPEP 2141 states, "The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made

explicit. The Court quoting In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "[R]ejections on obviousness cannot be sustained by mere conclusatory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" KSR, 550 U.S. at ,82 USPQ2d at 1396. Exemplary rationales that may support a conclusion of obviousness include: (A) Combining prior art elements according to known methods to yield predictable results; (B) Simple substitution of one known element for another to obtain predictable results; (C) Use of known technique to improve similar devices (methods, or products) in the same way; (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (E) " Obvious to try " choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention."

According to the rationale discussed in KSR above, the rationale in (A) and (F) above are seen to be applicable here since based on the prior art teachings, L-carnitine, other amino acids and the components as instantly claimed are known to improve protein synthesis in skeletal muscles and provide diet supplements to promote muscle adaptation. Thus, it is obvious to combine prior art elements and improve the product of the prior art to yield predictable results.

Thus, the claimed invention as a whole is prima facie obvious over the combined teachings of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 1623

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